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Practitioner's Docket No. U 015837-4

#### Optional Customer No. Bar Code



CHAPTER II

# TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/IB2003/000003

6 JANUARY 2003

TITLE OF INVENTION

#### A PROCESS FOR THE MANUFACTURE OF CEFPODOXIME PROXETIL

APPLICANT(S)

- 1. GHARPURE, Milind Moreshwar
- 2. DESHMUKH, Sanjay, Shankar
- 3. MAHALE, Rajendra, Dagesing

Mail Stop PCT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

**ATTENTION: EO/US** 

#### **CERTIFICATION UNDER 37 C.F.R. 1.10\***

(Express Mail label number is mandatory.) (Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date <u>July 6, 2005</u>, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number <u>EV 480460485 US</u>, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

GERALDINE MARTI

(type or print name of person mailing paper)

Signature of person mailing paper

WARNING:

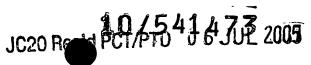
Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

\*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement

will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.



NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than the expiration of 30 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495(a) and (b).

**WARNING**:

Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. §1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing - See 37 C.F.R. §1.8.

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111. 37 C.F.R. § 1.494(f).

- 1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:
  - a. [X] This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).
  - b. [X] The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:
  - c. [ ] ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: § 1.495 Entering the national stage in the United States of America.

- (a) The applicant in an international application must fulfill the requirements of 35 U.S.C 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. The thirty month time period set forth in paragraphs (b), (c) (d), (e) and (h) of this section may not be extended. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.
- (b) To avoid abandonment of the application, the applicant shall furnish to the United Stats Patent and Trademark Office not later than the expiration of thirty months from the priority date:
- (1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and
  - (2) The basic national fee (see § 1.492(a)).
- (c)(1) If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date, the Office will notify the applicant if he or she has omitted any of:
- (i) A translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2));
- (ii) The oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1;
  - (ii) The search fee set forth in § 1.492(c); and
  - (iv) The examination fee set forth in § 1.492(c); and
  - (v) Any application size fee required by § 1.492(j)

- (2) A notice under paragraph (c)(1) of this section will set a period of time with which applicant must provide any omitted translation, oath or declaration of the inventor, search fee set forth in § 1.492(b), examination fee set forth in § 1.492(c), and any application size fee required by § 1.492(j) in order to avoid abandonment of the application.
- (3) The payment of the processing fee set forth in  $\S$  1.492(i) is required for acceptance of English translation later than the expiration of thirty months after the priority date. The payment of the surcharge set forth in  $\S$  1.429(h) is required for acceptance of the oath or declaration the inventor later than the expiration of thirty months after the priority date.

#### 2. Fees

TOTAL CLAIMS*   17	CLAIMS FEE *	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
FILING FEES**    Rational Fee   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)    Robert   Reduction by ½ for filing by small entity, if applicable. Statement may also be filed (note 37 CFR 1.9, 1.27, 1.28)	122	TOTAL CLAIMS*			x \$ 50.00 =	
FILING FEES**  [x] Basic filing Fee [x] Non-U.S. Search Report (\$500.00) [] No Search Report (\$500.00) [] Exam Fee not paid to U. S. (\$200.00) [] Search and Exam fee with U.S. WO or IPER conditions not satisfied (\$100.00) [] Search and Exam fee with U.S. WO or IPER conditions satisfied (\$0.00)  [] Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is \$250 for each additional 50 sheets paper or fraction thereof (\$ )  SMALL ENTITY    Reduction by ½ for filing by small entity, if applicable. Statement may also be filed. (note 37 CFR 1.9, 1.27, 1.28)    Subtotal		INDEPENDENT			Î	
Sample   S		MULTIPLE DEPENDI	ENT CLAIM(S) (if ap	plicable) + \$360.0	0	Not paid at this time
SMALL ENTITY  Reduction by ½ for filing by small entity, if applicable. Statement may also be filed. (note 37 CFR 1.9, 1.27, 1.28)  Subtotal  Total National Fee \$ 900.00  Fee for recording the enclosed assignment document \$40.00 (37 CFR 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".		[x] Basic filing [x] Non-U.S. S [] No Search [x] Exam Fee [] Search and or IPER co [] Search and or IPER co [] Additional drawings f sheets (ex or compute electronic i for each ad	g Fee Search Report file Report not paid to U. S. I Exam fee with U onditions not satis Exam fee with U onditions satisfied fee for specificate filed in paper over accluding sequence or program listing medium). The fee Iditional 50 sheets	ion and 100 slisting filed in is \$250 spaper or	400.00) 500.00) 200.00) 100.00)	\$300.00
		filed. (note 37 CFR 1.9,  Fee for recording the en	-			
		(See Item 13 below). Se				

<sup>\*</sup>May include Preliminary Amendment (see page 8) reducing the number of claims.

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	i. ii.	į j F	Please c	in the amount of \$900.00 to cover the above fees is enclosed.  narge Account No. 12-0425 in the amount of \$  of this sheet is enclosed.		
Trademark Office not later than the expiration of 30 mo		Office no	nent of the application the applicant shall furnish to the United States Patent and it later than the expiration of 30 months from the priority date: * * * (2) the basic 492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).			
WARNING:		If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.				
	[]	Assertion	of Sm	ıll Entity Status		
	[ ]	[ ] a		asserts status as a small entity under 37 C.F.R. § 1.27 by. ent or Written Assertion attached.		
NOTE:	37 C.F.R or by pay	. § 1.27(c) a ment as a sr	leals with nall entit	the assertion of small entity status, whether by a written specific declaration thereof of the basic filing fee or the fee for the entry into the national phase as states:		
		should mak entity statu establish si entitlement	te a deter s based mall entit to small	all entity status. Any party (person, small business concern or nonprofit organization) mination, pursuant to paragraph (f) of this section, of entitlement to be accorded small on the definitions set forth in paragraph (a) of this section, and must, in order to y status for the purpose of paying small entity fees, actually make an assertion of entity status, in the manner set forth in paragraph (c)(1) or (c)(3) of this section, in the tin which such small entity fees are to be paid.		
				by writing. Small entity status may be established by a written assertion of entitlement tity status. A written assertion must:		
		(	i)	Be clearly identifiable;		

Be signed (see paragraph (c)(2) of this section); and

to comply with the assertion requirement.

(ii)

(iii)

(i)

(ii)

assertion;

(2)

Convey the concept of entitlement to small entity status, such as by stating that

applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order

One of the parties identified in §§ 1.33(b) (e.g., an attorney or agent registered with the

Office), §§ 3.73(b) of this chapter notwithstanding, who can also file the written

At least one of the individuals identified as an inventor (even though a §§ 1.63 executed oath or declaration has not been submitted), notwithstanding §§ 1.33(b)(4), who can also file the written assertion pursuant to the exception under §§ 1.33(b) of this part;

Parties who can sign and file the written assertion. The written assertion can be signed by:

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- (iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.773(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under §§ 1.33(b) of this part.
- (3) Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4) or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.
  - (i) If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in §§ 1.16(e) or §§ 1.16(l).
  - (ii) The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."
- 3. [x] A copy of the International application as filed (35 U.S.C. 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

	a.	is transmitted herewith.
	b.	is not required, as the application was filed with the United States Receiving
		Office.
	c.	[x] has been transmitted
		i. [x] by the International Bureau.
		Date of mailing of the application (from form PCT/IB/308): 22 JULY 2004
		ii. [ ] by applicant on
		Date
١.	[x]	A translation of the International application into the English language (35 U.S.C.
	[]	371(c)(2)):
	a.	is transmitted herewith.
	b.	[x] is not required as the application was filed in English.
	c.	was previously transmitted by applicant on
	-	Date
	d.	[ ] will follow.

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) . . . applicant will be so notified and given a period of time within which to file the translation . . . in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of thirty months after the priority date . . . . A 'Sequence Listing' need not be translated if the "Sequence Listing' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b)."

5.	[x]		ments to the claims of the International application under PCT Article 19 (35 371(c)(3)):	
NOTE:	The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and c practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment fixection 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or errors may be corrected." 1147 O.G. 29-40, at 36.			
NOTE:	amendn <b>thirty</b> m	nents into E ionths from	l): "A copy of any amendments to the claims made under PCT Article 19, and a translation of those Inglish, if they were made in another language, must be furnished not later than the expiration of the priority date. Amendments under PCT Article 19 which are not received by the expiration of the priority date will be considered to be canceled."	
	a.	[]	are transmitted herewith.	
	b.		have been transmitted	
	-	i.	[ ] by the International Bureau.	
			Date of mailing of the amendment (from form PCT/IB/308):	
		ii.	[ ] by applicant on	
	c.	[x]	have not been transmitted as	
		i.	[x] applicant chose not to make amendments under PCT Article 19.  Date of mailing of Search Report (from form PCT/ISA/210): 06 JUNE  2003	
		ii.	the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.	
6.	[x] A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):			
	a.	[]	is transmitted herewith.	
	b.	ij	will follow	
	c.	ίi	is not required as the amendments were made in the English language.	
	d.	[x]	has not been transmitted for reasons indicated at point 5(c) above.	
7.	[x]		of the international examination report (PCT/IPEA/409)	
		[x]	is transmitted herewith. is not required as the application was filed with the United States Receiving Office.	
8.	[]	Annex(	(es) to the international preliminary examination report	
	a.	[ ]	is/are transmitted herewith.	
	b.	[]	is/are not required as the application was filed with the United States Receiving Office.	

9.	[ ]	A trans	A translation of the annexes to the international preliminary examination report			
NOTE:	37 C.F.R. § 1.497(e) "A translation into English of any annexes to an international preliminary examination rep (if applicable), if the annexes were made in another language, must be furnished not later than the expiration of the months form the priority date. Translations of the annexes which are not received by the expiration of thirty mon from the priority date may be submitted within any period set pursuant to paragraph (c) of this section accompan by the processing fee set forth in § 1.492(f). Annexes for which translations are not timely received will be conside canceled."					
	a. b.	[]	is transmitted herewith. is not required as the annexes are in the English language.			
10.	[x]	[x] An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115				
	a.	[]	was previously submitted by applicant on  Date			
	b.	[ ] i.	is submitted herewith, and such oath or declaration  [ ] is attached to the application.			
		ii.	identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. 1.70.			
	<b>c.</b> .	[x]	will follow.			
NOTE:	37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the oath or declaration in order to prevent abandonment of the application The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."					
Other of	documen	t(s) or in	nformation included:			
11.	[x]	An Inte	ernational Search Report (PCT/ISA/210) or Declaration under PCT Article			
	a.	[x]	is transmitted herewith.			
	b.	[]	has been transmitted by the International Bureau.  Date of mailing (from form PCT/IB/308):			
	c.	[ ]	is not required, as the application was searched by the United States International Searching Authority.			
	d.	[]	will be transmitted promptly upon request.			
	e.	[ ]	has been submitted by applicant on			
			Date			
12.	[x]	An Info	ormation Disclosure Statement under 37 C.F.R. 1.97 and 1.98:			
	a.	[x]	is transmitted herewith.			
		[v]	Also transmitted herewith is/are: Form PTO-1449 (PTO/SB/08A and 08B).			
		[x] [x]	Copies of citations listed.			
,	b.	[ ]	will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).			
	c.	[]	was previously submitted by applicant on			
			Date			

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13.	[]	An assignment document is transmitted herewith for recording.
		erate [] "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING PATENT APPLICATION" or [] FORM PTO 1595 is also attached.
14.	[x]	Additional documents:
	a.	[ ] Copy of request (PCT/RO/101)
	b.	[x] International Publication No. WO 2004/060896 A1
		i. [x] Specification, claims and drawing
		ii. [] Front page only
	c.	Preliminary amendment (37 C.F.R. § 1.121)
	d.	[x] Other
		FORM PCT/IB/301
		FORM PCT/IB/308
		FORM PCT/ISA/202
		FORM PCT/ISA/220
		FORM PCT/ISA/224
		FORM PCT/IPEA/402
		FORM PCT/IPEA/408 (WRITTEN OPINION)
		COPY OF RESPONSE TO WRITTEN OPINION
		DATED 4 DECEMBER 2004
		FORM PCT/IPEA/416
15.	[x]	The above checked items are being transmitted
	a.	[x] before 30 months from any claimed priority date.
	b.	[ ] after 30 months.
16.	[]	Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on , namely:

#### **AUTHORIZATION TO CHARGE ADDITIONAL FEES**

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

				16-36 DARGERTO O. S. HILL 2005			
	[X]	The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425.					
		[X]	37 C.F.R. 1.492(a)(1)	(basic filing fee)			
WARNI	NG:	Because results i	failure to pay the national fe n abandonment of the applica	we within 30 months without extension (37 C.F.R. $\S$ 1.495(b)(2)) ation, it would be best to always check the above box.			
		[]	37 C.F.R. 1.492(b)	(search fee)			
		į	37 C.F.R. 1.492(b)	(exam fee)			
		[]	37 C.F.R. 1.492(b)	(claim fees)			
NOTE:	be paid o in any no	r these cl tice of fe	aims cancelled by amendmen	lependent claims not paid on filing or on later presentation must only t prior to the expiration of the time period set for response by the PTO 92(d)), it might be best not to authorize the PTO to charge additional mendments after final action.			
		[X]	37 C.F.R. 1.16(s) (spe	ec and drawing, each 50 pages over 100)			
		[X]	37 C.F.R. 1.17 (applied				
		[X]	37 C.F.R. 1.17(a)(1)-(	(5) (extension fees pursuant to § 1.136(a).			
NOTE:	application notification	on pr on of ch	ior to paying, or at the time of ange of status must be madured if the change is to anoth 37 C.F.R. § 1.492(e)	and (f) (surcharge fees for filing the declaration and/or lation of an International Application later than 30			
		[X]	Please credit any over	payments to deposit account 12-0425.			
				SIGNATURE OF PRACTITIONER			
Reg. N	o.: 25,85	8		William R. Evans (type or print name of practitioner)			
Tel. No.: (212)708-1930				P.O. Address			
Custor	ner No.: (	00140		c/o Ladas & Parry LLP 26 West 61st Street			
100111001170	 	11781		New York, N.Y. 10023			
		11681					

PATENT TRADEMARK OFFICE

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